REMARKS

Claims 30-39 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for lacking antecedent basis for the second and third lids. Applicant has amended claims 30 and 34 at the portions indicated in the Office Action to correct such lack of antecedent basis. Accordingly, Applicant believes that the rejection should be withdrawn. Entry of the amendment should be made because such amendment resolves an outstanding issue and creates no new issues, thereby reducing the number of issues present for any appeal.

Claims 30, 31, 34, 35, 36, 38, and 39 stand rejected under 35 U.S.C 103(a) as being unpatentable over Smith (hereinafter referred to as "Smith '611") in view of Smith (hereinafter referred to as "Smith '567"). The Examiner considered that Smith '611 disclosed a sterile medical container having a first frangible lid (17, 23) and a second outer lid (28) having a syringe-receiving stopper (31). The Examiner then noted that Smith '567 disclosed a sterile medical container having a frangible member and further noted that such reference added a third outer lid (100) to help maintain the sterile environment. The Examiner then concluded that it would be obvious to add an outer lid to the medical container of Smith '611 in view of the Smith '567 patent to keep contaminants off its outer surface. The Examiner further stated that it would be obvious to use a capsule to deliver the solid component of the mixture and that the method steps would be provided by the proposed combination. Applicant respectfully disagrees with the Examiner's conclusion for the reasons set forth more fully below.

As mentioned by the Examiner, the container of Smith '611 does not include an additional (third) outer lid. However, Applicant includes an outer lid to preserve sterility of its middle lid and its syringe receiving stopper portion prior to and after the time the solid

constituent breaks through the lower most lid and enters into the container to be combined with the liquid constituent. At such stage, the combined solid and liquid constituents in the container are preserved as sterile by the middle and outer lids upon breakage of the lower lid. Sterility is also maintained by the middle lid when the top lid is removed in preparation for dispensing of the contents of the container. Accordingly, the syringe-receiving stopper must be located in the middle lid for the dispenser to function as described above. The lower lid must be sufficiently weak to permit breakage when pressure is applied to the solid constituent. With such function in mind, it is clear that the outer lid is critical to the overall attainment of sterility.

The Examiner has attempted to compensate for the lack of an outer (third) lid in Smith '611 by stating that Smith '567 teaches adding a third outer lid to help maintain a sterile environment. The aspect of sterility is not mentioned in Smith '567. However, of more importance is that Smith '567 discloses that a sealing material, such as wax, may be included in the container. It is clear that the wax is actually a coating that is integral to, and not removable from, metal cap 98 (outer lid of Smith '567). Accordingly, there is no "third outer lid" disclosed in Smith '567; and thus, such patent cannot provide a teaching to compensate for the lack of such lid in Smith '611. It is submitted that the advantageous functions of such outer lid enjoyed by Applicant are not obvious. It is further noted that Smith '611 does not teach use of a capsule (see claims 31 and 35) as the solid component. Such capsule penetrates the lower lid and enters into the container, thereby functioning to assist such penetration. Smith '611 appears to utilize granular material rather than a capsule. Applicant submits that the claimed invention would not be obvious to one of ordinary skill in the art for the reasons set forth above.

Claims 30, 33, 34, and 36-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Smith '611 in view of Crankshaw et al. The Examiner considered that Smith '611 disclosed the claimed invention except for the presence of a third sterile lid. The Examiner further considered that Crankshaw et al. taught the addition of an outer sterile lid to keep contaminants off the stopper and then concluded that an addition of an outer lid to the Smith '611 device would be obvious. Applicant respectfully disagrees with the Examiner's conclusion for the reasons set forth below.

Smith '611 has been fully discussed above and such discussion is referred to, but not repeated, so as to not unduly burden the instant record. The Examiner considered that Crankshaw et al. taught the use of an outer sterile lid to keep contaminants off the stopper and that the use of such lid would be an obvious addition to the container of Smith '611. As considered by the Examiner, dust cover 36 the Crankshaw et al. container may be removably secured to sleeve 32 of cap member 37 to function as a dust cover for stopper 20. Dust cover 36 appears to be the only lid-type structure disclosed by Crankshaw et al. In any event, Cranshaw et al.'s stopper 20 is not included in a middle lid, as required by the instant claims. It is evident that the containers of Smith '611 and Crankshaw et al. are quire distinct in function and operation. Moreover, stopper 17 of Smith '611 is already protected from dust by closure member 28. Thus, adding an additional protective member such as disclosed by Crankshaw et al. would be redundant, and thereby unnecessary, because such function already exists in the container of Smith '611. In other words, one of ordinary skill in the art would not find it obvious to add an additional cover to a device already containing such a cover. On the other hand, Applicant's cover is advantageous to the operation of the claimed container and method for reasons already

discussed extensively above. These advantageous features lead to the conclusion that the claimed constituent delivery system and method are of an unobvious nature.

Claim 32 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Smith '611 in view of Smith '567 or, alternatively, over Smith '611 in view of Crankshaw et al. The Examiner considered that either of the above combinations taken further in view of Barasch et al. would be obvious. As pointed out by the Examiner, Barasch et al. discloses a mixing vial having well to assist in withdrawal of material from the vial.

Applicant has already extensively presented reasons in support of the nonobviousness of rejections based upon Smith '611 in view of Smith '567 and of Smith '611 in view of Crankshaw et al. Such reasons are hereby repeated. The addition of the teachings of Barasch et al. to the teachings of other references cannot overcome the deficiencies of the combination of Smith '611, Smith '567, and Crankshaw et al. Accordingly, claim 32 should also be regarded as containing nonobvious subject matter.

In summary, it is emphasized that the three lids of Applicant have a cooperative function, and that all three lids must be present and have specific properties and structure for the system of the invention to operate in its advantageous mode. During operation of the system, sufficient pressure is applied to a portion of the top lid and transmitted through the middle lid to the solid constituent to cause the solid constituent, which is sterilely contained between the middle and bottom lids, to press against and break the lower lid. Upon such breakage, the solid constituent enters the liquid-containing container where the solid and liquid constituents are combined. Sterility of both constituents, as well as the middle and bottom lids, is preserved because such procedure is conducted while all three lids remain in sealed relationship. Sterility is maintained

throughout the dispensing procedure because removal of the top lid exposes the second lid, which remains sterile because its sterility was protected by the top lid during penetration of the solid constituent into the container holding the liquid constituent. Insertion of a syringe into the syringe-receiving stopper located in the middle lid enables the user to withdraw a desired amount of sterile combined product at one time or during selected intervals. It is submitted that the above-enumerated advantages underscore the unobvious nature of the claimed constituent delivery system and method.

In view of the amendment of claims 30 and 34 to provide proper antecedent basis and the accompanying remarks, Applicant believes that the instant amendment should be entered because such entry resolves an issue and raises no new issues. Upon such entry, Applicant submits that the application is in condition for allowance; and notice of to such effect is respectfully requested.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

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